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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,058	01/08/2002	Kanji Takada	2001-1874A	5848

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WASHINGTON, DC 20006-1021

EXAMINER

AZPURU, CARLOS A

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/14/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/030,058

Applicant(s)

TAKADA ET AL.

Examiner

Carlos A. Azpuru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### **DETAILED ACTION**

Receipt is acknowledged of the priority document, information disclosure statement, and preliminary amendment filed 01/08/03. A supplemental information disclosure statement was filed on 07/23/02.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 5, and 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 5 refer to ratios of glycyrrhizin to ester of 1:0.05-10 and 1:0.05-10, respectively. Clarification is requested in that this appears to be a two way ratio, written for three components. Also, if applicant contemplates the range to include a range of 0.05 –10, the ratios should be rewritten as two complete ratios. For example, 1: 0.05 to 1:10. Clarification and correction is requested.

Applicant has set out a transmucosal drug delivery system which functions by crossing oral, vaginal or rectal mucosa. The bioactive delivered ultimately works through its systemic therapeutic levels. This claim points out that delivery is through the oral mucosa in claim 7. Therefore, it is unclear how the drug is released in the large intestine. Clarification is requested since it is unclear whether applicant is actually

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claiming a transmucosal system, or an oral delivery system such as a capsule or tablet whose coating is selective for delivery to the large intestine. Further, it is suggested applicant refer to an "oral transmucosal" preparation in order to clarify this issue.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by EPO'704.

EPO'704 discloses a glycyrrhizin preparation for transmucosal composition in admixture with an ester mixture of a fatty acid glycerol ester and a fatty acid macrogol ester. The fatty acid may be saturated. The macrogol molecular weight is within 100 to 800, and the ratio of glycyrrhizin to ester ration is 1:0.1-10. Chelating agents, organic acids, and surfactants are included. The drug delivery system may be in the form of a rectal or vaginal suppository (see Abstract; page 2, line 41 to Page 3, line 30; example 3). The instant claims are anticipated by EPO'704.

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Claims 1-6, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by JP'424.

JP'424 discloses a glycyrrhizin preparation for transmucosal composition in admixture with an ester mixture of a fatty acid glycerol ester and a fatty acid macrogol ester. The fatty acid may be saturated. The macrogol molecular weight is within 100 to 800, and the ratio of glycyrrhizin to ester ration is 1:0.1-10. Chelating agents, organic acids, and surfactants are included. The drugf delivery system may be in the form of a rectal or vaginal suppository (see Abstract). The instant claims are anticipated by JP'424

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by JP'955. JP'955 discloses a glycyrrhizin preparation for transmucosal composition in admixture with an ester mixture of a fatty acid glycerol ester and a fatty acid macrogol ester. The fatty acid may be saturated. The macrogol molecular weight is within 100 to 800, and the ratio of glycyrrhizin to ester ration is 1:0.1-10. Chelating agents, organic acids, and surfactants are included (see Abstract). The instant claims are anticipated by JP'955

***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP'731, in view of WO'622.

JP'731 discloses a preparation for intrarectal administration containing glycyrrhizin and a fatty base (see claims; page 2, upper right column). JP'731 differs from the instant claims in that a fatty acid ester mixture is not specifically recited.

In a similar transmucosal composition, WO'622 teaches that Labrosol is suitable for enhancing absorption of a bioactive (see page 2, lines 30-33; Examples 9-12, 15, 17, and 22-25). Labrosol is a mixture comprising a fatty acid glycerol and a fatty acid macrogol ester (see page 4 of the description). Therefore, it would have been well within the skill of the ordinary practitioner to use Labrosol as taught by WO'622 as the specific fatty base used in the transmucosal delivery of glycyrrhizin as taught by JP'731. Modification of the JP'731 with the use Labrosol would produce the expected result of enhanced transmucosal delivery as taught by both references not only for fats in general, but for Labrosol in particular. Those of ordinary skill would therefore expect similar therapeutic results from the transmucosal delivery of such an agent utilizing a fatty acid glycerol ester/fatty acid macrogol ester mixture. The incorporation of Labrosol

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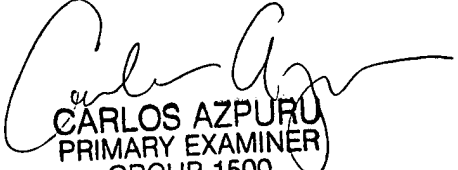
as taught by WO'622 into the composition as taught by JP'731 would have been obvious to those of ordinary skill.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is 703/308-0237. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

ca  
July 10, 2003

  
CARLOS AZPURU  
PRIMARY EXAMINER  
GROUP 1500